

SPECIALTY GUIDELINE MANAGEMENT

ISTODAX (romidepsin) romidepsin (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy
2. Peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy

B. Compendial Uses

1. Mycosis fungoides (MF)/Sézary syndrome (SS)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. **Cutaneous T-cell lymphoma (CTCL)**

Authorization of 12 months may be granted for treatment of CTCL (e.g., mycosis fungoides, Sézary syndrome, primary cutaneous anaplastic large cell lymphoma).

B. **Peripheral T-cell lymphoma (PTCL)** (see Appendix)

Authorization of 12 months may be granted for treatment of PTCL.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. APPENDIX: PTCL subtypes

1. Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
2. Angioimmunoblastic T-cell lymphoma (AITL)
3. Anaplastic large cell lymphoma (ALCL), anaplastic lymphoma kinase (ALK)+/ALK-
4. Breast Implant-Associated ALCL
5. Enteropathy-associated T-cell lymphoma (EATL)
6. Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
7. Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)

Reference number
1859-A

8. Follicular T-cell lymphoma (FTCL)
9. Extranodal NK/T-cell lymphoma, nasal type (ENKL)
10. Hepatosplenic T-cell lymphoma (HSTCL)

V. REFERENCES

1. Istodax [package insert]. Summit, NJ: Celgene Corp.; October 2020.
2. Romidepsin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2020.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 6, 2021.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas (Version 1.2021). <https://www.nccn.org>. Accessed January 7, 2021.